Type IIIb endoleak and relining: a mathematical model on distraction forces

Abstract

Purpose :

Stent graft degradation with type IIIb endoleak represents a serious complication of endovascular aneurysm repair. Relining is often undertaken but the consequences to graft stability are unknown. This study aimed to develop a mathematical model to predict the changes in distraction force following relining of a stent graft using the Nellix (Endologix, Irvine Ca., USA) endovascular sealing device and a Renu (Cook, Bloomington In., USA) unilateral stent graft.

Mathematical model :

The mathematical model was based on pressure and volume flow through the stent grafts and incorporated recognised distraction force equations. Steady flow was presumed at peak systolic pressures to calculate the maximum distraction force experienced, with gravity ignored. Distraction forces for 28-36mm diameter stent graft bodies with 16mm limbs were calculated and compared to forces following relining with single and two Nellix devices, and the Renu unilateral device. Distraction forces for 28mm, 32mm, and 36mm stent grafts were 5.99N, 10.21N, 14.99N respectively. Similar forces were reported for bilateral Nellix devices after relining (5.86N, 10.08N, 14.86N respectively). However, use of a unilateral Nellix increased distraction forces: 9.92N, 14.14N, 18.92N respectively. These were comparable to the increase observed after relining with a Renu unilateral stent graft: 9.87N, 14.09N, 18.86N respectively. The proportional increase in distraction force for a unilateral re-lining ranged from 26-66%, with the greatest increase noted in the smaller diameter main body.

Conclusion :

Relining a stent graft with a type IIIb endoleak using bilateral Nellix devices does not increase distraction force. A unilateral device or the Renu system, however, could theoretically increase the distraction force by up to 66%, potentially risking migration and Type Ia endoleak. In clinical practice, theses results suggest that a relining with bilateral Nellix should be preferred to the Renu unilateral stent graft.

Keywords: abdominal aortic aneurysm, endoleak, endograft, polymer, models

Text

Introduction

Treatment of type IIIb endoleak after conventional EVAR can take several forms. It may be treated through open operation and explantation of the original device, albeit with significant morbidity and mortality.[1] An alternative endovascular solution is to reline the original device with another bifurcated or aorto-uniiliac stent-graft.[2] The endovascular re-lining technique may be complicated, however, due to the length of the main body component of the original device precluding incorporation of a standard graft. Fenestrated cuffed devices with or without internalised contralateral limbs may be required in order to reline the fabric defect whilst accommodating the dimensions of a short bodied device.[3] Nellix has been used to reline EVAR stent-grafts in the setting of endoleak and impending failure.[4,5]. We recently treated with success 3 cases of late endoleak type III using the Nellix device. The insertion of the Nellix stent or Renu unilateral stent-graft within a standard stent graft will inevitably change the haemodynamic forces experienced at the aortic neck and within the iliac vessels. There may be a disadvantageous increase in the distraction force, potentially causing subsequent migration of the combined stents and prompting type I endoleak.

The aim of the study is to present a mathematical model investigating the changes in distraction force following relining of a conventional aortic stent-graft using the Nellix endovascular sealing device and a Renu unilateral stent graft.

Mathematical model

To model the haemodynamic forces both in a standard endovascular stent graft and in the Nellix Endovascular Aneurysm Sealing System containing endobags, one can, for the *fluid forces*, use a standard control volume approach[6] based on the principles of conservation of mass and momentum. Such an approach, in combination with Bernoulli's equation to link velocities and pressures, has been successfully used by various authors[7-11] to estimate distraction forces in endovascular[7-9] or endoluminal[10] stents or in modelling of haemodynamic forces in the aortic arch[11] for example. Haemodynamic distraction forces are generated by blood pressure and blood flow and may encourage migration of the stent graft. To calculate these fluid forces we apply a control volume around the "wetted" part of the geometry we wish to consider – as shown schematically in Figure 1 by the blue dashed-lines – and then apply equations (1) and (2) from Jones et al[7] to determine the change in fluid momentum in the axial (flow) direction and hence the fluid component of the distraction force (shown in blue in Figure 1). The flow is assumed to be quasi-steady, gravity forces are neglected, and conditions are chosen to represent peak systole in the supraceliac aorta at rest. This included a constant pressure of 140 mm Hg and a constant volume flow rate of 8 litres/min (=1.323x 10^{-4} m^3/s)[12] assuming a density of 1098 kg/m^3. Forces for different morphologies, i.e. proximal and distal diameters, are shown in Table 1.

For the Nellix system there are also forces exerted on the solid polymer endobags which need to be considered. To do so one resolves the pressure forces in the "vertical" direction (vertical as shown in Figure 1 but we note that gravity forces are still neglected). At the proximal face this pressure force acts downwards and is equal to the peak systolic blood pressure multiplied by the endobag facial area A_N (e.g. for the double stent case $A_N = 0.25\pi D^2 - 0.5\pi d_N^2$) whereas the force at the distal end pushes against this force in the upwards direction and, for the double stent, is equal to the distal pressure (determined using Bernouilli's equation) multiplied by twice the distal facial area A_n ($A_n = 0.25\pi D^2 - 0.25\pi d_N^2$) as there are two distal ends. For the single stent case, the proximal facial area is increased ($= 0.25\pi D^2 - 0.25\pi d_N^2$) and it is assumed that the non-stented limb is occluded such that no pressure force can be exerted on this face. All forces – both the fluid control volume force and the endobag force – are shown for some representative morphologies in Table 1.

Overall it is apparent that for the Nellix double stent configuration, the overall distraction force is essentially the same as the force in the standard endovascular stent graft case as the large reduction in fluidic distraction force is almost exactly balanced by a significant downwards pressure force exerted on the endobag. For the Nellix single-stent configuration, which is assumed to be "missing" one half of the restoring pressure force acting on the distal ends as it is assumed occluded and at zero pressure, it can be seen that the distraction forces are significantly greater. The proportional increase in distraction force for a unilateral re-lining ranged from 26-66%, with the greatest increase noted in the smaller diameter main body.

Discussion

The mathematical model indicates that the distraction force experienced by the combined original stent graft and the Nellix stent is essentially unchanged following re-lining. This only applies, however, to the case of bilateral re-lining, with Nellix stents deployed in both iliac limbs. The situation is different if an aorto-uniiliac re-lining is performed. In such circumstances there is a significant increase in the distraction force experienced by the device, dependent on the original graft dimensions. The proportional increase in distraction force for a unilateral re-lining ranged from 26-66%, with the greatest increase noted in the smaller diameter main body. In clinical practice, theses results suggest that a relining with bilateral Nellix should be preferred to the Renu unilateral stent graft.

When the Nellix is deployed in an aortic aneurysm the stability of the device is dependant on the cured polymer filling the lumen in its entirety. However, when used for re-lining, the Nellix stents are entirely reliant on the original fixation of the primary stent graft. It is therefore paramount that the quality of fixation must be carefully assessed, including close inspection for disengagement or shearing of the barbs before the re-lining is performed. If there has been proximal or distal stent migration then the fixation may be inadequate and re-lining with a sealing device may expose the patient to the risk of subsequent type I endoleak.[13] The original stent graft fixation could be reinforced through the use of endo-anchors prior to re-lining, however, the validity of this method is unknown.[14] Nellix associated with chimney technique has been described in juxta-renal aneurysm treatment and common iliac artery aneurysm with inadequate landing zone.[15] There is therefore a potential for using chimneys in relining with proximal protrusion. Indeed, there is the possibility to extend the proximal and distal sealing zones by inserting sufficiently long Nellix stents (120-180mm) to allow protrusion of the endobags beyond the top of the fabric of the original graft. This may allow treatment of type I endoleaks, however, consideration of the position of renal arteries and iliac bifurcation is important if undertaking this. A concomitant treatment of unclear type IIIb and Ia endoleak is therefore feasible.

According to EUROSTAR data, the reported incidence of late type III endoleak after successful EVAR is reported to be approximately 2-3%[16,17] and it has been reported with three commercially available endoprostheses.[18-20] The source of these endoleaks is difficult to identify despite multi-modal imaging, as demonstrated in this illustrated case (figure2a). Sometimes, differential diagnosis with type IV or type V endoleak is very difficult. Indeed, Type III endoleaks should be treated promptly and in an analysis of preliminary EUROSTAR data, patients with late type III endoleaks had 9 times greater chance of aneurysm rupture compared with other registry patients.[21] Furthermore, type III endoleak is the second commonest cause of post-EVAR aneurysm rupture.[22] Treatment can be endovascular or open. A conservative policy carrie a definite, but undefined rupture risk, whilst an open conversion has significant physiological implications due to the aortic clamping. Endovascular options can be limited due to the main body length of the original endograft being too short to allow deployment of a second standard bifurcated device. Insertion of a Cook Renu graft associated with a femoro-femoral cross over bypass and a plug in the contralateral leg is an option.[23] The Nellix can seal any fabric defects (type IIIb, IV, V endoleak) but will not treat concurrent type II endoleak (figure 2b, 2c). The use of sealing technology to re-line grafts is very simple and the majority of the procedure can be done under fluoroscopic imaging only, as the metal stent of the original graft will guide accurate placement of the Nellix stents. This offers clear advantages in terms of operative time, contrast medium load and radiation dose over re-lining with fenestrated cuffs in short bodied stent grafts, which is a complicated and long procedure.

Following re-lining, a close surveillance is mandatory. Cessation of sac growth may confirm the diagnosis of type IIIb endoleak and through regular imaging any concerns regarding fixation and migration can be monitored. Early CTA followed by regular Duplex and AXR may be sufficient since, following re-lining, the aneurysm repair is once again reliant on the original stent graft.[24]

Conclusion

Relining a stent graft with a type IIIb endoleak using bilateral Nellix devices does not increase distraction force. In theory, distraction forces on the original stent graft remain unchanged if bilateral Nellix stents are deployed, but increase significantly if a uni-lateral procedure is performed. In clinical practice, theses results suggest that a relining with bilateral Nellix should be preferred to the Renu unilateral stent graft.

References

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Table 1: Estimated forces for different stent-graft morphologies (assuming fixed constant pressure of 140 mm Hg, fixed bifurcation angle of 30°, fixed diameter of Nellix stent of 10 mm and a constant volume flow rate of 8 litres/min assuming a density of 1098 kg/m^3 in all cases)

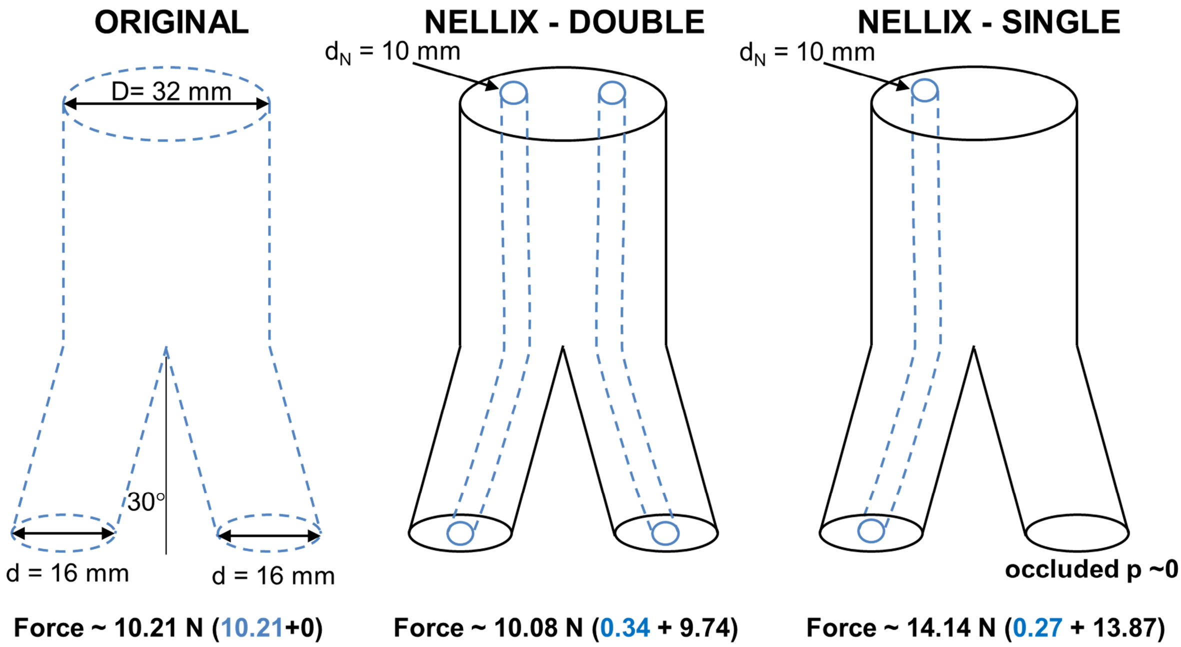
	D (mm)	D (mm)	Fluid force (N)	Endobag force (N)	Total force (N)
Original	28	16	5.99	-	5.99
Original	32	16	10.21	-	10.21
Original	36	16	14.99	-	14.99
Nellix (double)	28	16	0.34	5.52	5.86
Nellix (double)	32	16	0.34	9.74	10.08
Nellix (double)	36	16	0.34	14.52	14.86
Nellix (single)	28	16	0.27	9.65	9.92
Nellix (single)	32	16	0.27	13.87	14.14
Nellix (single)	36	16	0.27	18.65	18.92

Figure Legends

Figure 1. Schematic diagram illustrating control volumes (shown with blue dashed lines) for standard fenestrated endovascular stent graft ("ORIGINAL") and the Nellix Endovascular Aneurysm Sealing System containing endobags in the double ("NELLIX-DOUBLE") and single stent ("NELLIX-SINGLE") configuration together with geometry of endobags (black lines). Forces determined using conditions provided in Table 1.

Figure 2a. DSA. Confirmation of type IIIb endoleak arising from the fabric just above the top of the controlateral limb (left). The catheter passed freely through this hole into the aneurysm.

Figures 2b. and 2c. CTA (MPR view). This figure shows the absence of type IIIb endoleak post relining by 2 Nellix stents.



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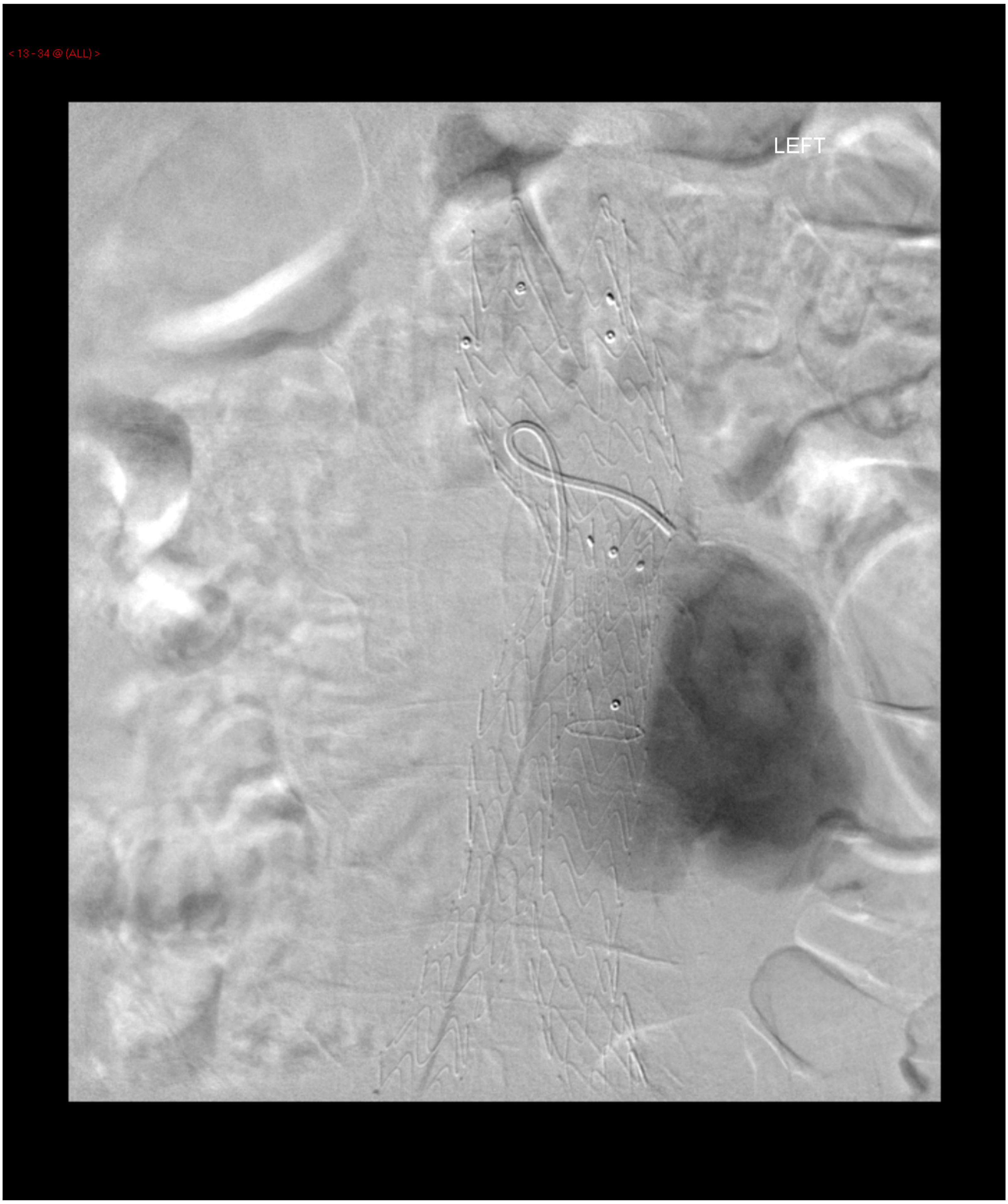

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